

K 094013 #1/5

TORNIER

MAY - 5 2011

Implants Chirurgicaux

Summary of Safety and Effectiveness information *Special 510(k) Premarket Notification – HLS KNEETEC System*

Date prepared: May 5th, 2011

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) Device name

Trade name: HLS KNEETEC System
Common name: Total anatomical knee prosthesis
Classification name: 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
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4) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: 87 JWH

5) Equivalent / Predicate device

HLS Noetos System, Tornier, K013906
PFC Modular Plus Offset Tibial Tray, DePuy, Inc., K984158
NexGen Complete Knee Solution Legacy Posterior Stabilized, Zimmer, K991581
AGC Total Knee System, Biomet, Inc., K833021, K912245, K984054



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S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

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K094013#2/5

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6) Device description

The HLS Kneetec prosthesis is intended for use as a semi-constrained replacement system. The HLS Kneetec cemented prosthesis with fixed tibial insert consists of three components intended to be used with bone cement: the femoral implant, the tibial implant and the patella. The tibial implant consists of two components: tibial insert and tibial tray, the tibial insert is clipped on the tibial tray. The tibial tray can be extended by a stem. The patella of the joint may be preserved or resurfaced with the patellar implant shared by all ranges of the HLS Kneetec prostheses.

The present device modification submission consists of the addition of a new prosthesis named HLS Kneetec to the HLS Knee range. The HLS Kneetec prosthesis is an evolution of the HLS Noetos System, CE marked in Europe since 1996 and cleared in the USA since 2001 (K013906). The HLS Kneetec prosthesis keeps HLS Noetos benefits and improves the compliance with patient's anatomy, with a new design to provide better bone coverage and greater interchangeability between sizes.

The HLS Kneetec System completes the Tornier HLS range of knee implants.

7) Materials

Femoral and tibial implants are manufactured from chromium cobalt alloy according to ISO 5832-4. The tibial plug is made of chromium cobalt alloy (CoCr) according to ISO standard 5832-7 or ISO standard 5832-12. Tibial inserts and the patella are made of ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2.

8) Indications for use

This device is indicated for use as a total knee replacement for the relief of pain and significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis.

It is also intended for the revision of knee prostheses.

The HLS Kneetec is intended for cemented use only.



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K094013 #3/5

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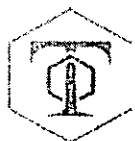
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9) Summary of technological characteristics

Main features or system characteristics		HLS Kneetec System	HLS Noetos System	PFC Modular Plus Offset Tibial Tray	NexGen Complete Knee solution Legacy Posterior Stabilized	AGC Total Knee System
Materials	Femoral part	CoCr alloy	CoCr alloy	CoCr alloy	CoCr alloy	CoCr alloy + Titanium alloy
	Tibial insert	UHMWPE	UHMWPE	UHMWPE	UHMWPE	UHMWPE
	Tibial tray	CoCr alloy	CoCr alloy	Titanium alloy	Titanium alloy	CoCr alloy + Titanium alloy
	Patella	UHMWPE	UHMWPE	UHMWPE	UHMWPE	UHMWPE
Postero stabilized		yes	yes	yes	yes	yes
Sizes	Femoral part	9 Right 9 Left	6 Right 6 Left	6 Right 6 Left	7 Right 7 Left	6 Right 6 Left
	Tibial insert	6 sizes 6 thicknesses	6 sizes 6 thicknesses	6 sizes 8 thicknesses	8 sizes 6 thicknesses	8 sizes 6 thicknesses
	Tibial tray	7 sizes	6 sizes	6 sizes	8 sizes	8 sizes
	Patella	4 diameters	3 diameters	4 diameters	5 diameters	3 diameters
Method of fixation		Cemented	Cemented	Cemented	Cemented	Cemented (interlok)
Indications for use		Total knee replacement	Total knee replacement	Total knee replacement	Total knee replacement	Total knee replacement
Terminal sterilization		Gamma	Gamma	Gamma	Gamma	Gamma
Manufacturer		TORNIER	TORNIER	DePuy	Zimmer	Biomet
K-number		K094013	K013906	K984158	K991581	K984054 K912245 K833021

The indications for use, the technical characteristics (materials, manufacturing principle, method of fixation), the packaging and the sterilization process of the new HLS Kneetec System are similar or identical to the predicate devices.

The different technical characteristics of the new HLS Kneetec System compared to the predicate devices are a new design of the tibial tray, a new femoral trochlear groove design with a new patella dome design. The new design of the HLS Kneetec System compared to the predicate HLS Noetos (K0143906) provides a better bone coverage and a greater interchangeability between sizes.



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10) Non-clinical testing

Non-clinical testing was not necessary to determinate substantial equivalence between the new HLS Kneetec System and the cited predicate devices about:

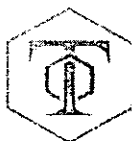
- The indications for use of the new HLS Kneetec System are identical to the indications for use of the predicate HLS Noetos System (K013906) and are very similar with the other predicates the PFC Modular Plus Offset Tibial Tray (K984158), the NexGen Complete Knee solution Legacy Posterior Stabilized (K991581) and the AGC Total Knee System (K833021, K912245, K984054).
- The intended use of the new HLS Kneetec System are identical to the intended use of predicates HLS Noetos System (K013906), PFC Modular Plus Offset Tibial Tray (K984158), NexGen Complete Knee solution Legacy Posterior Stabilized (K991581) and AGC Total Knee System (K833021, K912245, K984054).
- The raw materials of the new components of the HLS Kneetec System are identical to the raw materials of predicate HLS Noetos System (K013906).
- The fixation method of the new components of the HLS Kneetec is identical to the fixation method of the predicate components of the HLS Noetos (K013906), the PFC Modular Plus Offset Tibial Tray (K984158), the NexGen Complete Knee solution Legacy Posterior Stabilized (K991581) and the AGC Total Knee System (K833021, K912245, K984054). 1379, and K091751).

Non clinical testing was necessary to determinate substantial equivalence between the new HLS Kneetec System and the cited predicate devices about:

- The new design of the femoral component:
A contact area stress / pressure test was performed to compare contact pressure on UHMWPE tibial insert between the HLS Kneetec size 2 and the predicate HLS Noetos size 1 (K013906- Equivalent size) at each flexion angle.
The acceptance criteria is: the contact area stress and the contact pressure between the new HLS Kneetec size 2 and the predicate HLS Noetos size 1 (K013906- Equivalent size) must be equivalent.
Results of verification: there is no significant difference between the HLS Kneetec size 2 and the predicate HLS Noetos size 1 (K013906), the contact area stress /pressure is equivalent between the two prostheses.
So, the HLS Kneetec size 2 and the cleared HLS Noetos size 1(K013906) are equivalent.

Constraint test was performed to determine the constraint forces in anterior-posterior displacement, medial-lateral displacement and internal-external rotation between the HLS Kneetec size 2 and the predicate HLS Noetos size 1 (K013906 – Equivalent size) according to ASTM F1223.
The acceptance criteria is: load displacement curves must be equivalent to the predicate device HLS Noetos (K013906).
Results of verification: there is no significant difference between the HLS Kneetec size 2 and the predicate HLS Noetos size 1 (K013906), the frame of load displacement curves is equivalent between the two prostheses.
So, the HLS Kneetec size 2 and the cleared HLS Noetos size 1(K013906) are equivalent.

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- The new tibial tray design:
A fatigue test on the fixed Kneetec tibial tray was done to validate the fixed tibial tray of the HLS Kneetec following existing standards (Fatigue tests: ASTM F1800:2007 & NF ISO 14879-1:2000). The acceptance criteria is: the fixed tibial tray tested must resist to 10 millions of cycles without any damages.
Results of verification: five fixed tibial trays have been tested during 10 millions of cycles under maximum load of 237daN. No damage nor ruptures have been noted on the five fixed tibial trays.
So, the new tibial tray of the HLS Kneetec is conformed to the standards.
- The new femoral trochlear groove design with a new patella dome design:
A comparative study was done to verify that the new design of the trochlea has equivalent congruence with the new patella. We have conducted a comparative test versus the marketed predicate device HLS Noetos size 1(K013906) on the worst case component HLS Kneetec size 2 (equivalent size) to study the tracking of the patella under quadriceps motion.
The acceptance criteria is: the contact area and trajectories must be equivalent to the predicate device HLS Noetos (K013906).
Results of verification: for the HLS Kneetec and the predicate HLS Noetos (K013906) the principle is the same, the tracking of the patella is steady when moving the quadriceps in each position.
So, the design of the patella and the patella groove between the new HLS Kneetec and the cleared HLS Noetos (K013906) are equivalent.

Results of engineering studies referenced in this 510(k) submission demonstrate the proposed HLS Kneetec System device is substantially equivalent to the predicate devices.

11) Substantial equivalence conclusion

Based upon this comparative study, substantial equivalence of the new HLS Kneetec System to the already cleared components of the predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The components of the HLS Kneetec System are compared to the predicate devices.
- The components of the HLS Kneetec System have the same intended use as the HLS Noetos System, the PFC Modular Plus Offset Tibial Tray, the NexGen Complete Knee solution Legacy Posterior Stabilized and the AGC Total Knee System and very similar indications for use.
- Major technological characteristics are equivalent between the HLS Kneetec System and the predicate devices:
 - Equivalence of general features
 - Equivalent polyethylene thickness
 - Equivalent materials
 - Equivalent means of fixation
 - Equivalent prosthetic dimensions

Therefore, in light of the above information, the company believes that the components of the HLS Kneetec System may be cleared via the 510(k) notification process for use as a total knee prosthesis.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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% Ms. Severine Bonneton
Regulatory Affairs Specialist
161, rue Lavoisier - Montbonnot
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MAY - 5 2011

Re: K094013

Trade/Device Name: HLS KNEETEC System

Regulation Number: 21 CFR 88.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained
cemented prosthesis

Regulatory Class: Class II

Product Code: JWH

Dated: April 26, 2011

Received: April 29, 2011

Dear Ms. Bonneton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

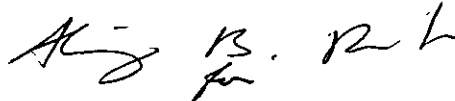
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson
Director

Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094013

Device Name: HLS KNEETEC System

Indications For Use:

This device is indicated for use as a total knee replacement for the relief of pain and significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis. This device is also intended for the revision of knee prostheses.

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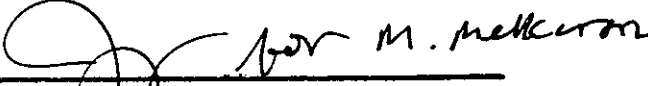
Prescription Use ☒ X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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